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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/327,199 | 06/07/99 | KADDURAH-DAOUK | AVZ-016 |

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HM22/1120

EXAMINER

TRIVERS, R

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

11/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/327,199

Applicant(s)

Kaddurak-Daouk

Examiner

RUSSELL TRAVERS

Group Art Unit

1617



☒ Responsive to communication(s) filed on May 6, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

The amendment filed June 5, 2000 has been received and entered into the file.

Claims 1-24 are presented for examination.

Applicant's Information disclosure statement failed to include copies of the references. Examiner obtained copies of the issued U.S. Patents listed, and these patents have been considered. Absent submission of the remaining references these publications can not be considered.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,

Art Unit:

- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither a "energy kinase modulator" or a "energy transmitting kinase modulator". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "energy kinase modulator" or "energy transmitting kinase modulator" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "energy kinase modulator(s)" or all "energy transmitting kinase modulator(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Art Unit:

Claims 1-4 and 6-24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-4 and 6-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 6-24 are rendered indefinite by the phrases "energy kinase modulator" or "energy transmitting kinase modulator" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are an "energy kinase modulator" or "energy transmitting kinase modulator" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's phrases fail to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 16-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals &

Art Unit:

Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303, as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claim 16 recites the broad recitation of a "energy kinase modulator", and the claim also recites, situations wherein the energy state "does not involve creatine kinase", which is a narrower statement of the range/limitation. Applicants recitation of the broad range or limitation together with a narrow range or limitation renders independent claim 16 and dependant claims 17-23 properly rejected as indefinite.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 8-14, 16-19, 21-22 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Maneesub et al or Behl et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-24 are rejected under 35 U.S.C. § 103 as being unpatentable

Maneesub et al and Behl et al.

Maneesub et al and Behl et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating neurodegenerative disorders as herein claimed. Claims 1-7, 8-14, 16-19, 21-22 and 24, and the primary references, differ as to:

- 1) failing to recited the instant mechanism of action, and
- 2) administration of the medicaments to humans therapeutically.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Art Unit:

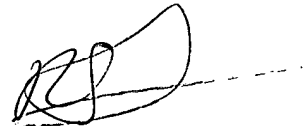
The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Art Unit:

Claims 9, 15, 20 and 23 specifically requires human administration. Maneesub et al employed the claimed compound therapeutically in rodents. The skilled artisan would have seen therapeutic success in rodents as a predictor of success in humans. Thus, possessing the Maneesub et al teaching the skilled artisan would have employed the Maneesub et al compositions therapeutically in humans and enjoyed a reasonable expectation of therapeutic success.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to read 'RT', with a horizontal line extending to the right.

**Russell Travers
Primary Examiner
Art Unit 1617**